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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,889	09/26/2006	Ryouichi Hoshino	279348US0PCT	4450

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
03/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,889	HOSHINO ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-4 are included in the prosecution.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 1/30/06 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masahiro et al. (JP 2001-055367).

The claimed invention is an oral solid dosage form having (S)-2-[3-[N-[4-(4-fluorophenoxy)benzyl]carbamoyl]-4-methoxybenzyl]butanoic acid (hereinafter

abbreviated as KRP-101) as an effective ingredient and comprising KRP-101 and additives.

Masahiro teaches a substituted phenylpropanoic acid derivative (Abstract and claims 1-35). Applicant states that according to Masahiro (JP 2001-55367), KRP-101 is publicly known as a derivative of substituted phenylpropanoic acid (Specification, Page 1, lines 10-12).

Masahiro does not expressly teach an oral solid dosage form having KRP-101 and additives.

It would have obvious to one of ordinary skill in the art to make a dosage form comprising KRP-101 and add additives appropriate for a desired dosage form. Since a tablet is a known oral solid dosage form, one with ordinary skill in the art would use tableting excipients and additives to formulate an oral dosage form of KRP-101. Formulating active ingredients into solid dosage forms (such as tablets) is well known in the pharmaceutical product development art.

Regarding instant claim 1, the limitation of the KRP-101 is taught by Masahiro (Abstract and claims 1-35). The limitation of the additives in an oral solid dosage form would have been obvious to one with ordinary skill in the art because formulating an oral solid dosage form with additives is well known in the pharmaceutical product development art.

6. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masahiro et al. (JP 2001-055367) in view of Takahashi et al. (US 4,619,938).

The teaching of Masahiro is stated above.

Masahiro does not expressly teach an oral solid dosage form having KRP-101 and additives.

Takahashi teaches tablets that are formulated with carriers or excipients (Col. 3, lines 5-7). A tablet composition comprising excipients crystalline cellulose and lactose, hydroxypropylcellulose, and magnesium stearate (lubricant) is disclosed (Col. 14, lines 29-30). "The active drug is mixed with the excipients, the disintegrator and the bonder to a uniform blend. The blend is granulated, and the granules are mixed with the lubricant. The mixture is formed under compression into tablets. As needed, the tablets thus obtained may be coated with an appropriate coating agent (for example, hydroxypropylmethylcellulose or shellac)" (Col. 14, lines 31-41).

It would have obvious to one of ordinary skill in the art to make a dosage form comprising the active compound KRP-101, as suggested by Masahiro, combine it with the excipients and additives for a tableting composition, as taught by Takahashi, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because formulating active ingredients into solid dosage forms (such as tablets) is well known in the pharmaceutical product development art and Takahashi teaches the specific tableting excipients and additives into an oral solid dosage form.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 2-3, the limitations of the additives would have been obvious over the crystalline cellulose, lactose (excipients), hydroxypropylcellulose (disintegrator), magnesium stearate (lubricant) and hydroxypropylmethylcellulose (coating) taught by Takahashi (Col. 14, lines 19-41).

Regarding instant claim 4, the product by process claim would have been obvious over the steps taught by Takahashi which include blending, granulation, compression and coating (Col. 14, lines 31-41). The limitation of dilution of the active ingredient KRP-101 with excipients is well known in the pharmaceutical product development art as a method to ensure uniformity of small quantities of active ingredients in the final dosage form. For instance, in a geometric dilution, equal amounts of active ingredient and excipient are blended. Then, additional excipient equal to the sum of the first blend (of active ingredient and excipient) is added to the first blend and mixed, and so on.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615